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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,581	06/05/2001	Gary M. Fader	BB-1339	6372

7590 10/19/2004  
Lori Y Beardell  
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Wilmington, DE 19898

EXAMINER

RAMIREZ, DELIA M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/857,581

Applicant(s)

FADER ET AL.

Examiner

Delia M. Ramirez

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 14 September 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.

Claim(s) objected to: NONE.

Claim(s) rejected: 1,3,4,11-19,26 and 29-33.

Claim(s) withdrawn from consideration: 51-69.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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***ADVISORY ACTION***

1. Claims 1, 3-4, 11-19, 26, 29-33, 51-69 are pending.
2. Applicant's submission of an alignment in Appendix A, a new sequence listing in electronic and paper form, and a declaration under 37 CFR 1.131 by inventor Brian McGonigle signed by all inventors filed on 9/14/2004 are acknowledged.
3. While the declaration begins with the statement "I, Dr. Brian McGonigle", instead of "We, [name of all inventors]", in view of a statement by inventor Brian McGonigle on page 1 of the declaration indicating that the invention was conceived and reduced to practice by all the inventors: Gary Fader, Woosuk Jung, Joan Odell, Xiaodan Yu and Brian McGonigle, as well as the fact that the declaration is signed by all the inventors, this declaration has been considered proper. In view of this submission, the 35 USC 102(a) rejection of claims 1, 3-4, 11-12, 26 and 29 previously applied over the teachings of Steele et al. is hereby withdrawn. Also, in view of the declaration submitted, and due to the fact that Siminsky et al. alone does not teach, suggest or render obvious the invention of claims 17-19 and 30-33, the previous 35 USC 103(a) rejection of these claims is hereby withdrawn.
4. The request for entering amendments to the specification and claims 1, 4, 14, 69, canceling of claim 3, adding claims 70-72, and arguments filed on 9/14/2004 under 37 CFR 1.116 in reply to the Final Action mailed on 3/10/2004 are acknowledged. The proposed amendments to the claims and the specification have been considered but will not be entered. While amendments to the claims seem to overcome the objections, the 35 USC 112, second paragraph rejections, the 35 USC 102(b) rejection of claim 3 over the teachings of Siminsky et al., and the 35 USC 112, first paragraph rejection of claim 3 due to its cancellation, the proposed amendments to the claims do not overcome the 35 USC 112, first paragraph written description and scope of enablement rejections previously applied to claim 4, the new matter rejection of claims 1, 11-19, 26, 29-33, and raise additional issues which would require further consideration as discussed below.

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5. The proposed amendments to the specification would be objected to as introducing new matter into the disclosure. While Applicants have submitted an alignment in Appendix A in support of the amendment to SEQ ID NO: 66, it is noted that there is no support in the specification as originally filed for amino acids Glu or Asp at position 292 or amino acids Gln or His at position 293. It is noted that while the original sequence listing indicate that positions 292 and 293 are open to any amino acid, and the specification as originally filed at page 42 provides support for amino acids Thr or Ile at position 294, there is no indication in page 42 as originally filed as to the amino acids which can be placed at position 292. Similarly, while page 42 of the specification as originally filed indicate that amino acids Glu or Asp can be placed at position 293, there is no support for amino acids Gln or His at position 293. Thus, there is no support in the sequence listing or the specification as originally filed for the new sequence listing or the proposed amendments to the specification.

6. New claim 70 would be rejected under 35 USC 112, second paragraph as being indefinite due to the recitation of "nucleic acid fragment of claim 4" as there is no antecedent basis for a fragment in claim 4.

7. New claim 70 would be objected to as it is essentially a duplicate of claim 1.

8. New claim 72 would be rejected under 35 USC 112, second paragraph as being indefinite due to the recitation of "the isolated nucleic acid of claim 71 wherein the polypeptide has the amino acid sequence as set forth in SEQ ID NO: 66" since the polypeptide of SEQ ID NO: 2 is a species of the genus of polypeptides comprising SEQ ID NO: 66, and the genus of polypeptides comprising SEQ ID NO: 66 encompass species having less than 95% sequence identity to the polypeptide of SEQ ID NO: 2. As such, the claim would not further limit claim 71.

9. Proposed amended claims 1, 14, claims 11-13, 15-19, 26, 29-33 would remain rejected and new claims 70-72 would be rejected under 35 USC 112, first paragraph as containing new matter. SEQ ID NO: 66 as amended in the sequence listing and the specification is no longer the same SEQ ID NO: 66 as

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originally filed in view of the fact that the amino acids at positions 292 and 293 have changed. See explanation above regarding the introduction of new matter in the specification. Therefore, proposed amended claims 1, 14, claims 11-13, 15-19, 26, 29-33 and new claims 70-72 would be directed to nucleic acids, transformed host cells, and methods of altering the level of expression of polypeptides for which there is no support in the specification. In addition, claims 1 as amended and new claims 70-72 are directed to a genus of nucleic acids which are not supported by the specification as originally filed. Therefore, claims directed to host cells transformed with the nucleic acids of claim 1 as amended, and methods of altering the level of expression of polypeptides encoded by the nucleic acids of amended claim 1 are also not supported by the specification as originally filed. Specifically, there is no support for (1) a genus of nucleic acids encoding isoflavone synthases comprising SEQ ID NO: 66 which excludes the nucleic acid of SEQ ID NO: 9, (2) a genus of nucleic acids encoding isoflavone synthases wherein the isoflavone synthases are 95% sequence identical to SEQ ID NO: 2 which excludes the nucleic acid of SEQ ID NO: 9, or (3) a genus of nucleic acids encoding isoflavone synthases wherein the isoflavone synthases are 95% sequence identical to SEQ ID NO: 2, comprise the amino acid sequence of SEQ ID NO: 66, and exclude the nucleic acid of SEQ ID NO: 9. While Applicants argue that (1) a person of skill in the art would have understood that the isolated nucleic acid of claim 1 should not have the nucleic acid sequence of SEQ ID NO: 9, and (2) the claims as originally filed included two claims, one directed to a nucleic acid encoding the polypeptide of SEQ ID NO: 66, and another directed to a nucleic acid encoding an isoflavone synthase wherein the nucleic acid cannot have SEQ ID NO: 9, therefore a nucleic acid encoding the polypeptide of SEQ ID NO: 66 would not include a nucleic acid comprising SEQ ID NO: 9, these arguments are not found persuasive. While one could argue that the genera of polynucleotides in claims 1 and 4 as originally filed are somewhat overlapping, claims 1 and 4 were originally filed as independent claims. Therefore, it is unclear as to how one can reasonably conclude that a preferred embodiment of the claimed invention is a subgenus of nucleic acids comprising the

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overlapping species of two independent claims. If a claim is directed to a genus of nucleic acids encoding polypeptides encoding a polypeptide comprising SEQ ID NO: 66, all species which fall within the genus are included. Only if the polynucleotide of SEQ ID NO: 9 does not encode a polypeptide comprising SEQ ID NO: 66, then that species is excluded. If, on the other hand, the polynucleotide of SEQ ID NO: 9 encodes the polypeptide of SEQ ID NO: 66, then that species is included in the claimed genus. Therefore, there is no evidence which shows that the genus of nucleic acids claimed was within the scope of the invention as conceived by Applicants at the time the application was filed.

10. Proposed amended claim 4 would remain rejected under 35 USC 112, first paragraph written description and scope of enablement for the reasons of record. While Applicants argue that the specification discloses several plant isoflavone synthases which are over 90% sequence identical, as indicated in the Final Action, the genus of nucleic acids claimed is not restricted to those sharing some structural elements but instead encompass any nucleic acid encoding any isoflavone synthase. Therefore, the genus of nucleic acids claimed is an extremely large and potentially structurally variable genus, and neither the specification nor the art provide any teaching indicating whether (1) all isoflavone synthases are 90% sequence identical to the consensus sequence of SEQ ID NO: 66, (2) all isoflavone synthase comprise SEQ ID NO: 66, or (3) all isoflavone synthases will have 521 amino acids. Thus, one cannot reasonably conclude that the claimed genus is adequately described. Furthermore, the specification is silent in regard to how to isolate/make those nucleic acids encoding any isoflavone synthase, which do not share any structural homology to the ones disclosed in the specification, and there is no evidence in the specification or the art as to whether all isoflavone synthases share the consensus sequence of SEQ ID NO: 66 or which are the structural elements in the consensus sequence of SEQ ID NO: 66 which are common to all isoflavone synthases. The art teaches the unpredictability of accurately assigning function based solely on structural homology, therefore, in view of what has been disclosed in the specification

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and the unpredictability of the art, one cannot reasonably conclude that the full scope of the claimed invention is enabled by the disclosure.

11. While withdrawn claims 51-69 have not been rejoined, it is noted that if rejoined, these claims would be rejected under 35 USC 112, second paragraph as indefinite due to the recitation of "nucleic acid fragment of claim 1" as lacking antecedent basis. Also, claims 51-69 would be rejected under 35 USC 112, first paragraph due to the introduction of new matter for the reasons indicated above in regard to proposed amended claim 1.

12. The objection of claim 4, rejection under 35 USC 112 second paragraph of claims 1, 11-19, 26, 29-33, new matter rejection of claims 1, 11-19, 26, 29-33, written description and scope of enablement rejection of claims 3-4, and 35 USC 102 (b) rejection of claim 3 previously applied are, therefore, maintained for the reasons of record in view of the non-entry of the proposed amendments.

13. For purposes of Appeal, the status of the claims is as follows:

Claim(s) allowed: NONE

Claims(s) objected to: NONE

Claim(s) rejected: 1, 3-4, 11-19, 26, 29-33

Claim(s) withdrawn from consideration: 51-69

14. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from

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either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
October 14, 2004

  
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PRIMARY EXAMINER  
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1600